K071541

510(k) Summary

SEP 10 2007

Manufacturer:	Small Bone Innovations International, SA Z.A. Les Bruyeres Peronnas France 01960
Submitted By:	Small Bone Innovations 1380 South Pennsylvania Avenue Morrisville, PA 19067
Proprietary Name:	SBi TwistoFIX
Classification name:	Class II, 888.3040 – Smooth or threaded metallic bone fixation fastener
Common/Usual Name:	Screw, Fixation, Bone
Product Code:	HWC
Substantial Equivalence:	Documentation is provided which demonstrated the SBi TwistoFIX to be substantially equivalent to other legally marketed devices.
Device Description:	The SBi TwistoFIX System consists of a set of titanium bone screws for internal fixation. The screws are machined on the end of a drill shank which inserts into a driver. After insertion of the screw into the bone, the drill shank twists off and breaks cleanly from the screw head. The devices are supplied non-sterile and are available in various sizes diameters and lengths.
Intended Use:	The SBi TwistoFIX is indicated for bone reconstruction, osteotomy, fracture repair, and fracture fixation of bones appropriate for the size of the device.
Material:	The implants are made from Ti-6Al-4V per ISO 5832-3

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 10 2007

Musculoskeletal Clinical Regulatory Advisers, LLC (MCRA)
% Small Bone Innovations International, SA
Mr. Robert Hoehn
Regulatory Associate
1380 S. Pennsylvania Avenue
Morrisville, PA 19067

Re: K071541
Trade/Device Name: SBI TwistoFIX
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: September 5, 2007
Received: September 7, 2007

Dear Mr. Hoehn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number:

Device Name: SBi TwistoFIX

Indications For Use:

The SBi TwistoFIX is indicated for bone reconstruction, osteotomy, fracture repair, and fracture fixation of bones appropriate for the size of the device.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071541